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June 5, 2025

VIA ECF

Honorable Brian R. Martinotti, U.S.D.J.
United States District Court
District of New Jersey
Frank Lautenberg Post Office &
U.S. Courthouse
2 Federal Plaza, 3rd Floor
Newark, NJ 07102

Honorable Rukhsanah L. Singh, U.S.M.J.
United States District Court
District of New Jersey
Clarkson S. Fisher Building &
U.S. Courthouse
402 East State St.
Trenton, NJ 08608

Re: *In re Insulin Pricing Litigation*, No. 2:23-md-3080 (BRM/RLS) | MDL No. 3080

Dear Judges Martinotti and Singh:

On behalf of Novo Nordisk Inc. ("NNI"), we write in response to Plaintiffs' May 29, 2025 request to file a motion for permission to propound requests for admission to NNI (the "Request"). The Court should reject Plaintiffs' ad hoc request to serve this set of RFAs and instead direct all parties to meet and confer regarding an amendment to the discovery plan with generally applicable guidelines for how RFAs may be served in this MDL.

A month ago, Plaintiffs sent NNI the proposed RFAs and asked whether NNI would oppose a request for leave to serve them, acknowledging that the operative case management orders do not permit service of RFAs at this time. During the lone meet-and-confer call between NNI and Plaintiffs on this topic on May 7, NNI explained that Plaintiffs' proposal was inefficient and would unnecessarily burden both the Court and parties, in addition to the fact that their RFAs seek irrelevant information. Instead of inviting serial requests for leave to serve RFAs, NNI suggested that the parties should negotiate an amendment to the relevant Case Management Order ("CMO") setting forth a procedure for service of RFAs, including deadlines and numeric limits applicable to all parties. On the call, Plaintiffs did not disagree with that suggestion; instead, they stated that they would need to discuss among themselves and would follow up with NNI. They never did. Without further discussing the issue with NNI, they filed their Request on May 29. Their failure to meaningfully meet and confer about the Request is reason enough to deny it.

Even if Plaintiffs had fulfilled their meet-and-confer obligation, the Court should deny the Request. It makes no sense to address discovery topics that will inevitably recur in this MDL via piecemeal letter briefing followed by piecemeal motion practice. Instead, the parties should meet and confer regarding an amendment to the discovery plan that would set an orderly process for serving and responding to RFAs. Once that is resolved, Plaintiffs can serve RFAs consistent with the terms of the amended CMO and the parties can raise any objections they may have to the substance of such discovery as part of that process.

Procedural History

On April 28, Plaintiffs sent NNI a copy of the proposed RFAs and asked whether NNI would oppose a request for leave to serve them. In response, NNI asked to confer with Plaintiffs;

the parties had a call on May 7. On that call, NNI noted that CMO #13—which "sets forth the procedures and timeline for Master Discovery Requests and other discovery at this stage" of the MDL (ECF No. 313 at 1)—is silent as to RFAs. NNI explained that Plaintiffs' proposal was inefficient, insofar as it would require the parties to meet and confer and engage in motion practice whenever *any* party seeks to serve any RFAs in this MDL. .Accordingly, NNI suggested that if Plaintiffs now wish to begin serving RFAs, the proper approach would be to propose an amendment to CMO #13 that would set limits on how many master RFAs may be served by the parties and a procedure for responding to them, similar to the provisions in that CMO governing other forms of written discovery. NNI noted that Plaintiffs' approach would impose unnecessary burdens on the Court by requiring it to resolve a motion whenever a party wants to serve any RFAs in this MDL.

On the call, Plaintiffs did not express disagreement with NNI's explanation of the procedural unwieldiness of their proposed RFAs. Instead, they indicated that they would need to discuss among the tracks. And in light of the procedural issues raised by NNI, Plaintiffs declined to respond to NNI's questions regarding the substance of the proposed RFAs, such as why contracts with a non-party to this litigation that are governed by separate federal statutory provisions—including contracts that fall outside the discovery time period set by the Court—would be a proper topic for discovery.

However, Plaintiffs never followed up with NNI. Indeed, NNI heard nothing further from Plaintiffs about the proposed RFAs until they filed their Request with the Court on May 29. This failure to meaningfully meet and confer was a violation of this Court's orders. *See* CMO #5 (ECF No. 127 at 2) (explaining that before any party "files a motion in this MDL, the parties must first meet and confer in good faith to attempt to resolve the issue(s)").

Argument

Plaintiffs' proposal to propound nearly 100 RFAs to NNI in an ad hoc fashion—and in lieu of establishing an organized process that would apply across the board to all parties—is both inefficient and inconsistent with this Court's orders. As this Court explained in the Initial Discovery Plan (CMO #10), it sought "to promote the just and efficient conduct of this litigation, conserve judicial and party resources, minimize duplicative discovery, and serve the convenience of the parties and witnesses." ECF No. 198 at 1. Those common-sense principles are even more essential in an MDL of this size. And consistent with those principles, the Court's subsequent order on master written discovery (CMO #13) imposed numerical limitations on both requests for production and interrogatories, as well as timelines and other strictures for those forms of discovery. ECF No. 313 at 2–4. Notably, the Court restricted the number of requests for production that Plaintiffs were allowed to serve—even though there are no limitations on such requests under the Federal Rules of Civil Procedure—and in doing so, rejected Plaintiffs' argument that they should be entitled to unlimited requests for production. *See* ECF No. 270 at 7–8 (Plaintiffs' contention that because "Rule 34 imposes no numerical limitation[s] . . . there is no valid basis to restrict the number of documents [sic] requests parties may serve").

CMO #13 does not include a provision governing RFAs. That is because the parties were not seeking to serve RFAs at the time that CMO was entered. And that, too, makes sense, given that CMO #13 governs written discovery at the initial "stage" of this MDL (ECF No. 313 at 1). Thus, it includes provisions governing requests for production and interrogatories, which litigants routinely serve in the early stages of fact discovery. By contrast, litigants ordinarily serve requests

for admission closer to the *end* of discovery—after the factual record is more fully developed, such that the admission of facts will clarify issues or potentially eliminate issues as the case proceeds to summary judgment and trial. *See Shelton v. Fast Advance Funding, LLC*, 805 F. App'x 156, 158 (3d Cir. 2020) ("[R]equests for admission typically come late in discovery, or even after discovery has been completed and trial is imminent. If at that point a party is served with a request for admission of a fact that it now knows to be true, it must admit that fact . . . . That is what Rule 36 was intended to do—narrow the issues for trial, or even altogether obviate the need for trial."); *see also Siani v. Suny Farmingdale*, 2009 WL 3254924, at *1 (E.D.N.Y. Oct. 7, 2009) (observing that "the use of Requests for Admissions at [the early] stage of a litigation is not desirable" because "requests are best used to narrow issues for trial, not to 'discover' information").

To be clear, NNI does not agree with Plaintiffs' self-serving description of their proposed RFAs or that they have any relevance to this litigation. Nor should the Court accept Plaintiffs' unsupported assertions about NNI's contract negotiations with a non-party (the VA), or their assertions about the purported details of those contracts. Courts in fact routinely conclude that discovery into "contracts that are not in dispute and involve different parties, terms, and surrounding circumstances [are] a 'fishing expedition.'" *Herman v. Seaworld Parks & Ent., Inc.*, 2016 WL 3746421, at *1 (M.D. Fla. July 13, 2016); *see also BNSF Ry. Co. v. Panhandle N. R.R. LLC*, 2018 WL 4076487, at *3 (N.D. Tex. Jan. 11, 2018) (explaining that third-party contracts are "the product of independent negotiations with different parties under different circumstances, and as such they are unlikely to be relevant to the instant case"). But that is not the issue before the Court, which need not evaluate the substance of these specific RFAs in evaluating this request. Instead, the issue is whether it makes sense to address the service of RFAs via a case management order that applies to all litigants, or whether such requests should be handled via individual pre-motion letter briefs (followed by full briefing) for each litigant who wishes—at any time, against any party, and without limit—to obtain an exception to existing case management orders that do not provide for the service of RFAs.

NNI notes that it is common for MDL courts to set guidelines for RFAs. In recent years, there are numerous examples of courts imposing limitations on the number of RFAs and establishing parameters for how they are to be propounded. *See, e.g.*, Ex. A (*In re: Denosumab Pat. Litig.*, 25-md-3138 (CPO-EAP) (D.N.J.), ECF No. 38-1 at 14–15 (limiting parties to twenty-five requests for admission each, exclusive of requests directed at authenticating documents)); Ex. B (*In re: Soclean, Inc., Mktg., Sale Prac., and Prod. Liab. Litig.*, No. 22-mc-0152 (W.D. Pa.), ECF No. 213 at 2 (limiting number of RFAs for both consumer class plaintiffs and defendant)); Ex. C (*In re Xarelto (Rivaroxaban) (310) Pat. Litig.*, No. 21-md-3017 (RGA) (D. Del.), ECF No. 13 at 2–3 (requiring "[t]he Plaintiff Groups" to "coordinate with one another" and permitting plaintiffs to "jointly serve up to 25 requests for admission on each Defendant Group," allowing the same number for the defendant groups, and permitting each group "up to 5 individualized requests for admission")); Ex. D (*In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 20-2930 (RGA) (D. Del.), ECF No. 92 at 5 (limiting plaintiffs to service of "fifty [] requests for admission on each Defendant Group," limiting defendants to service of "twenty-five . . . common requests for admission," and permitting defendants to serve an additional ten "nonduplicative requests for admission on Plaintiff" to be "directed solely to issues specific to that Defendant Group")).

NNI respectfully requests that the Court deny Plaintiffs' Request and instead order the parties to meet and confer regarding a general framework for RFAs. The parties can then submit either a joint proposal or competing proposals for an amendment to CMO #13 to encompass RFAs.

Respectfully submitted,

/s/ Brian W. Carroll

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: DENOSUMAB PATENT LITIGATION	1: 25-md-03138 (CPO-EAP)
This Document Relates To:	(MDL 3138)
Amgen, Inc. and Amgen Manufacturing, Ltd. v. Accord BioPharma, Inc., Accord Healthcare, Inc., and Intas Pharmaceuticals, Ltd., 1:25-cv-01305 (CPO-EAP) (MDL 3138)	

JOINT DISCOVERY PLAN

Pursuant to Federal Rule of Civil Procedure 26(f) and New Jersey Local Rules 26.1(a) and 26.1(b), Plaintiffs Amgen Inc. and Amgen Manufacturing Limited LLC (collectively, "Amgen") and Defendants Accord Biopharma, Inc., Accord Healthcare, Inc., and Intas Pharmaceuticals, Ltd. (collectively, "Accord") have conferred and submit the following Joint Discovery Plan.

1. **Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.**

   Counsel for each party is identified on the signature pages of this Joint Discovery Plan.

2. **Set forth a brief description of the case, including the causes of action and defenses asserted.**

   Amgen's Description of the Case

   This is another patent infringement action involving patents that cover denosumab, the active ingredient in Amgen's biologic drug products Prolia® and XGEVA®, and patents on innovative manufacturing processes for denosumab. Prolia and XGEVA have an established

track record, benefiting millions of patients who take these medicines to reduce the risk of serious bone fractures caused by osteoporosis and bone cancers. Accord, like Sandoz, Inc. ("Sandoz"); Celltrion, Inc. and Celltrion USA, Inc. ("Celltrion"); and Fresenius Kabi USA, LLC, Fresenius SwissBioSim GmbH, Fresenius Kabi Deutschland GmbH, and Fresenius Kabi Austria GmbH ("Fresenius") before it, seeks to capitalize on that established track record to sell copycat denosumab products ("biosimilars"). As the Court is aware, Amgen previously sued Sandoz and Celltrion in this Court, and both Sandoz and Celltrion settled with Amgen, agreeing to, among other things, the entry of permanent injunctions against them. Dkt. 437 in *Amgen v. Sandoz*, No. 1:23-cv-02406-CPO-EAP (D.N.J.); Dkt. 310 in *Amgen v. Celltrion*, No. 1:24-cv-06497-CPO-EAP (D.N.J.). Amgen also sued and settled its case against Fresenius. Dkt. 102 in *Amgen v. Fresenius*, No. 1:25-cv-01080-CP-EAP (D.N.J.). A complete list of such actions in this Court includes:

- *Amgen v. Sandoz*, No. 1:23-cv-02406-CPO-EAP (D.N.J.)
- *Amgen v. Celltrion*, No. 1:24-cv-06497-CPO-EAP (D.N.J.)
- *In re Subpoena to FujiFilm Irvine Scientific*, No. 1:24-cv-08830-CPO-EAP (D.N.J.)
- *In The Matter of the Application of Amgen Inc. for Assistance Before a Foreign Tribunal*, No. 2:24-cv-09052-CPO-EAP (D.N.J.)
- *Amgen v. Fresenius*, No. 1-25-cv-01080-CPO-EAP (D.N.J.)
- *Amgen v. Samsung*, No. 1:24-cv-08417-CPO-EAP (D.N.J.)

Accord, like Sandoz, Celltrion, Samsung, and Fresenius before it, has sought FDA approval to market its denosumab biosimilar products under an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs created under the Biologics Price

Competition and Innovation Act ("the BPCIA"), Pub. L. 111-148 § 7001 *et seq*.; 42 U.S.C. § 262(k). In this action, Amgen has asserted thirty-four patents against Accord: United States Patent Nos. 7,364,736; 7,662,930; 7,888,101; 7,928,205; 8,053,236; 8,058,418; 8,460,896; 8,680,248; 9,012,178; 9,133,493; 9,228,168; 9,320,816; 9,328,134; 9,359,435; 9,388,447; 10,106,829; 10,167,492; 10,227,627; 10,513,723; 10,583,397; 10,655,156; 10,822,630; 10,894,972; 11,077,404; 11,098,079; 11,130,980; 11,254,963; 11,299,760; 11,319,568; 11,434,514; 11,459,595; 11,946,085; 11,952,605; and 12,084,686 (collectively, the "Patents-in-Suit"). Each patent was duly issued by the United States Patent and Trademark Office after examination by technically trained patent examiners. As such, each patent is presumed valid, and Accord bears the heavy burden of proving invalidity by clear and convincing evidence.

The Patents-in-Suit span multiple different "families" of inventions, some focused on the denosumab antibody itself and novel pharmaceutical compositions comprising the antibody; and others cover innovative manufacturing processes developed at Amgen. Within each family, individual patents present different and unique issues of infringement and validity.

Accord's denosumab biosimilar products have infringed and will infringe the asserted antibody patents and various of Amgen's patented manufacturing processes (although, as addressed below, Accord has so far withheld information it is required by the BPCIA to provide in order to enable Amgen to fully assess a claim for infringement with respect to the manufacturing patents). And unless restrained, Accord's patent infringement will irreparably harm Amgen, just as Sandoz and Celltrion each agreed its launch would irreparably harm Amgen when they agreed to entry of permanent injunctions against them, Dkt. 437 at 2 in *Amgen v Sandoz*, No. 1:23-cv-02406-CPO-EAP (D.N.J.); Dkt. 310 at 2 in *Amgen v. Celltrion*, No. 1:24-cv-06497-CPO-EAP (D.N.J.). Manufacturing technologies like the ones covered by Amgen's

patents are "highly material" to biological product innovators (like Amgen) and biosimilar developers (like Accord) alike, and "were recognized as so during enactment" of the BPCIA by Congress. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1364 (Fed. Cir. 2015) (Newman, J., dissenting). They impact not only how much product can be made, but also the product's quality, safety, and characteristics such as potency and half-life, among other things. Well-controlled manufacturing processes can also play a critical role in securing regulatory approval for a drug product and, as here, in Accord's ability to obtain approval to sell its denosumab products as a "biosimilar" of Amgen's Prolia and XGEVA.

Amgen filed this action for patent infringement on November 13, 2024, against Accord, after months of pre-suit investigation and correspondence with Accord under the pre-litigation exchange procedures set forth in the BPCIA. Unfortunately, Accord failed to comply with its obligation to supply information regarding its manufacturing processes as required by the BPCIA. *See* 42 U.S.C. § 262(*l*)(2)(A) (requiring production of a copy of the BLA "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application").

During the BPCIA pre-litigation exchanges period, Amgen diligently evaluated the BLA that Accord produced and repeatedly requested Accord supplement its deficient production, including by identifying categories of missing information in correspondence on June 14, 2024, and again on July, 11, 2024. Although Accord supplemented its original production on June 28, 2024, the materials produced to Amgen remained deficient. The categories of missing information are now also captured in the document requests that Amgen served on March 21, 2025.

Despite Accord's failure to comply with (*l*)(2)(A) of the BPCIA, Amgen participated in

the exchange to the best of its ability based on the information available and provided Accord with a list of patents for which Amgen believes a claim of patent infringement could reasonably be asserted. Only after engaging with Accord for months seeking to remedy Accord's failings did Amgen resort to filing this action, its remedy under the BPCIA statute. *See* 42 U.S.C. § 262(*l*)(9)(C).

Accord's failure to comply with its obligations to produce manufacturing information under the BPCIA, not only authorizes this action but also entitles Amgen to fulsome early discovery from Accord. Only after receiving this discovery can Amgen appropriately focus this case (*e.g.*, narrow the asserted patents). 42 U.S.C. § 262(*l*)(9)(C); *Amgen Inc. v. Hospira Inc.*, 866 F.3d 1355, 1361–62 (Fed. Cir. 2017).

Below, Accord notes the fact that other biosimilars seeking authorization to market their denosumab biosimilar products withheld required documents under the BPCIA exchange, apparently suggesting that makes it appropriate for Accord to have done so. That is not correct. The Court is familiar with the extent of early discovery that was required in those prior cases in order to narrow the asserted patents, including discovery beyond just BLA documents. The same is true here as to Accord.

Accord's Description of the Case

This is a patent infringement civil action. Amgen has asserted 34 patents against Accord. The patents are directed to numerous different technologies including the chemical product, methods of manufacturing the chemical product, purification of the product, and feed media for the product.

The critical factual issues are defined by the numerous claims at issue in the 34 asserted patents, and issues of invalidity and infringement of those claims. The legal issues will relate to

those same questions of invalidity and infringement.

Accord intends to assert invalidity and noninfringement contentions regarding the asserted patents. Accord submits that Amgen must reduce the number of asserted patents and claims to a reasonable number before Accord must prepare and serve its invalidity and noninfringement contentions. Amgen has indicated that it anticipates narrowing the asserted patents following focused initial discovery. Accord submits that such focused initial discovery be undertaken before Accord must expend resources addressing initial invalidity and noninfringement contentions of up to 20 patents as Amgen proposes. (Dkt. 21-2 at PageID: 150.) Accord proposes an initial phase of litigation that enables the parties to reduce the number of patents at issue to preserve the parties' and court's resources.

As this is a civil action arising under the BPCIA, Accord has not begun marketing its competing product. Additionally, Accord stipulated to a preliminary injunction effective until October 1, 2025. Thus, there are no damages issues to consider in this matter.

Regarding Amgen's "Description of the Case," much of it is not related to the instant civil action and merits no response. Of some interest, however, is Amgen's retelling of the parties' pre-litigation BPCIA exchanges. Amgen's narrative is inaccurate, presumably to provide a pretext for Amgen's refusal to complete the information exchange procedure set out by the BPCIA and prematurely file its civil action against Accord. Amgen's allegations against Accord are strikingly similar to its allegations against Sandoz, Celltrion, Samsung Bioepis, and Fresenius.

The below is an excerpt from Amgen's complaint against Sandoz:

> Sandoz provided a copy of that BLA to Amgen Inc. even though it had not been accepted by the FDA (and would not be accepted until February 2023). Since then, **Amgen has diligently evaluated the BLA** that was provided and has participated in the prelitigation exchange contemplated under the BPCIA to the best of its ability. **Amgen's efforts,**

> **however, have been frustrated by Sandoz's initial and continued failure** to comply with subsection (l)(2)(A) of the BPCIA….

Amgen v. Sandoz, No. 1:23-cv-02406-CPO-EAP (D.N.J.), Dkt. 1 at PageID: 3 (emphases added).

> The below is an excerpt from Amgen's complaint against Celltrion:
>
> Defendants provided Amgen Inc.[redacted], which purports to show that the [redacted]. Defendants refused to provide any of the other requested information. Since receiving the BLA, **Amgen Inc. has diligently evaluated the BLA**, and has participated in the prelitigation exchange contemplated under the BPCIA to the best of its ability. **Amgen Inc.'s efforts, however, have been frustrated by Defendants' initial and continued failure** to comply with subsection (l)(2)(A) of the BPCIA….

Amgen v. Celltrion, No. 1:24-cv-06497-CPO-EAP (D.N.J.), Dkt. 1 at PageID: 3 (emphases added).

> The below is an excerpt from Amgen's complaint against Samsung Bioepis:
>
> Since receiving the Incomplete BLA, **Amgen Inc has diligently evaluated the unredacted portions** and repeatedly requested Bioepis correct and/or supplement their deficient production…. Amgen has participated in the pre-litigation exchange contemplated under the BPCIA to the best of its ability. **Amgen's efforts, however, have been frustrated by Defendants' initial and ongoing failure** to comply with subsection (l)(2)(A) of the BPCIA

Amgen v. Samsung, No. 1:24-cv-08417-CPO-EAP (D.N.J.), Dkt. 1 at p. 4 (emphases added).

> The below is an excerpt from Amgen's complaint against Fresenius:
>
> Since receiving the Incomplete BLA, **Amgen Inc has diligently evaluated the unredacted portions** and repeatedly requested Defendants correct and supplement their deficient production. … Amgen has participated in the pre-litigation exchange contemplated under the BPCIA to the best of its ability. **Amgen's efforts, however, have been frustrated by Defendants' initial and ongoing failure** to comply with subsection (l)(2)(A) of the BPCIA….

Amgen v. Fresenius, No. 1-24-cv-09555 (N. D. Ill.), Dkt. 1 at PageID #:4 (emphases added).

Amgen's pretext is not well taken and its assertion that it is entitled to "fulsome early discovery from Accord" as a result of alleged deficiencies is not supported. *See, infra,* 8.A., Accord's Position.

3. **Have settlement discussions taken place? Yes _X_ No ___**

In-house counsel for Amgen and Accord have engaged in initial and ongoing settlement discussions.

4. **The parties <u>have</u> met pursuant to Fed. R. Civ. P. 26(f).**

Amgen and Accord met pursuant to Fed. R. Civ. P. 26(f) on March 17, 2025, and April 4, 2025.

5. **The parties <u>have not</u> exchanged the information required by Fed. R. Civ. P. 26(a)(1).**

Amgen and Accord have agreed to exchange initial disclosures under Fed. R. Civ. P. 26(a)(1) on the date when Amgen must serve its L. Pat. R. 3.1 infringement contentions for the patents that overlap with the 20 narrowed patents in the *Samsung* case, as set forth by the Court's Scheduling Order (MDL ECF No. 30).

6. **Explain any problems in connection with completing the disclosures required by Fed R. Civ. P. 26(a)(1). If not, state the reason therefor.**

Neither Amgen nor Accord anticipates any problems in connection with completing the disclosures required by Fed. R. Civ. P. 26(a)(1).

7. **The parties <u>have not</u> filed disclosures of third-party litigation funding. See Local Civil Rule 7.1.1.**

Neither Amgen nor Accord was required to make a disclosure under L. Civ. R. 7.1.1 because Amgen has no third-party litigation funding in this case, and Accord has no third-party litigation funding in this case.

8. **The parties <u>have</u> conducted discovery other than the above disclosures. If so, describe.**

A. BPCIA Exchange

On May 13, 2024, Accord provided Amgen with access to a hard drive that Accord represented was a copy of its Biologics License Application submitted to the Secretary under 42

U.S.C. § 262(k) ("BLA"). On June 28, 2024, Accord produced additional documents to Amgen regarding its BLA.

Amgen's Position: Amgen's position is that these productions were insufficient to satisfy Accord's obligations under 42 U.S.C. § 262(*l*)(2)(A). Amgen looks forward to receiving Accord's productions on April 21, 2025 and May 23, 2025 as set forth in MDL ECF No. 30, ¶¶ 3, 8.

Accord's Position: Accord's position is that the productions were sufficient as they comprised all of the BLA documents in Accord's possession. During the BPCIA exchange, Accord advised Amgen that much of the information Amgen sought was not in Accord's possession, but in the possession of Accord's suppliers. Accord's suppliers offered to make the information available to Amgen under strict confidentiality disclosure restrictions, but Amgen refused those restrictions. Accord submits that Amgen will have to serve the necessary Rule 45 subpoenas in order to discover the information held by those Accord suppliers, and will have to negotiate an appropriate protective order with those suppliers.

B. Amgen's Discovery Requests

On March 21, 2025, after the initial Rule 26(f) conference on March 17, Amgen served on Accord a set of document requests (101 requests) and a set of interrogatories (16 interrogatories) directed at, among other things, the manufacturing information that Amgen contends Accord was required to produce under the BPCIA and that Amgen has requested from Accord since at least June 6 and July 11, 2024, as well as documents revealing Accord's actual launch plans and support for Accord's ability to achieve whatever are those launch plans.

Amgen's Position: Amgen's document requests and interrogatories were timely served on March 21, 2025 after the parties' initial Rule 26(f) conference on March 17, 2025. On April

17, 2025, Amgen identified as its priority requests 20 requests for production and 10 interrogatories from the sets it already served per the Court's Scheduling Order. MDL ECF No. 30, ¶ 2.

Accord's Position: As the current matters were stayed at the time (Dkt. 4 at PageID: 10, paragraph 12) until the Initial Case Management Conference, which was held on April 1, 2025, and Amgen's discovery requests were served before conclusion of the parties continuing Rule 26(f) conference, Amgen's discovery requests were not properly served. Additionally, pursuant to the Court Scheduling Order of April 15, 2025 (Dkt. 30), the parties are to "identify, per side, twenty (20) priority requests for production of documents and ten (10) interrogatories for initial reciprocal discovery" with completion of the priority discovery by May 23, 2025. On April 17, 2025, Amgen served on Accord an identification of its 20 priority requests for production and 10 priority interrogatories. Accord will respond according to the Court's Scheduling Order (Dkt. 30).

C. Accord's Discovery Requests

On April 17, 2025, Accord served on Amgen a set of document requests (11) and a set of interrogatories (5).

Amgen's Position: The Court has already rejected Accord's request (repeated below) that Amgen produce all Samsung's discovery requests and Amgen's responses and productions in response thereto. MDL ECF No. 30 at 1 n.1. And that was before Accord served its own requests. Now that it has, the parties can proceed with respect to Accord's requests.

Accord's Position: Separately, Accord requested that Amgen produce to Accord discovery requests served on Amgen and Amgen's documents Amgen has produced to Samsung in the Samsung case in response to Samsung's RFPs, and Amgen's responses to Samsung's

ROGs and RFAs in the Samsung case. (Dkt. 30 at PageID: 340, n. 1.) Accord has agreed that it will not serve discovery requests that are duplicates of those served by Samsung. (Dkt. 21 at PageID: 142.) Accord has further proposed that it will forgo raising any disputes of its own regarding Amgen's productions and responses to Samsung's written discovery from the Samsung case that have been addressed in the Samsung case.

9. Proposed Joint Discovery Plan

a. Discovery is needed on the following subjects:

Amgen's Discovery Subjects

At this time, Amgen anticipates that discovery, including of electronically stored information, such as computer-based or other digital information, and of samples of Accord's denosumab biosimilar drug substance and drug products taken during various stages of its manufacturing processes and of the final substance and products, will be needed from Accord and potentially third-parties on the following subjects:

- Accord's denosumab biosimilar drug substance and drug products, and the manufacturing thereof;
- Accord's submissions to or communications with the FDA regarding its denosumab biosimilar drug substance and drug products;
- Accord's manufacturing of its denosumab biosimilar drug substance and drug products;
- Accord's research, development, and testing of Accord's denosumab biosimilar products and its manufacturing process;
- Accord's comparison of Accord's denosumab biosimilar to Amgen's Prolia/XGEVA;

- Accord's investigation into and knowledge of the Patents-in-Suit;
- Accord's efforts, if any, to design around the Patents-in-Suit;
- Accord's clinical trials of Accord's denosumab biosimilar products;
- Accord's intended use(s) of Accord's denosumab biosimilar products;
- Accord's importation of Accord's denosumab biosimilar products into the United States;
- Accord's stockpiling of Accord's denosumab biosimilar products in the United States;
- Accord's launch plans and anticipated pre-marketing, marketing, advertising, and promotion of Accord's denosumab biosimilar products;
- Accord's non-infringement, invalidity, and unenforceability defenses, if any;
- Accord's assessment, analysis, and study of the value of denosumab and related manufacturing processes
- Accord's anticipated pricing of Accord's denosumab biosimilar products;
- Accord's contract negotiations, contracts, and rebate agreements with third-party payers regarding Accord's denosumab biosimilar products;
- Accord's communications with third-party payers regarding Accord's denosumab biosimilar products;
- Accord's actual and projected sales, revenues, and markets share for Accord's denosumab biosimilar products;
- Accord's actual and projected profits and costs for its denosumab biosimilar products;
- The corporate structure and financial status of Accord;

- Any alleged hardships Accord will suffer if injunctive relief is granted; and
- Any alleged harms to public interest if injunctive relief is granted.

The foregoing is a non-exhaustive list and Amgen expressly reserves the right to investigate and seek discovery on all areas relevant to the issues pertinent to this case, including the need to seek discovery on issues related to damages.

As to Accord's argument below that the scope of discovery should artificially be restricted to Accord's BLA with limited exceptions, Accord's position is inaccurate and is contrary to the Federal Rules (and the BPCIA). The scope of discovery is generally set by the pleadings, including the claims and defenses set forth in Amgen's Complaint and Accord's Answer. Indeed, Accord's participation in the BPCIA exchange required that even before a complaint was filed, Accord produce the needed information in addition to its BLA per 42 U.S.C. § 262(*l*)(2)(A), but Accord failed to do so.

Accord's Discovery Subjects

Discovery is needed on the issues of patent invalidity and infringement, including from third parties pursuant to Rule 45 subpoena practice. As the question of infringement are controlled by Accord's BLA, discovery should be limited in scope to the BLA and limited specific information outside of the BLA. As this is a civil action arising under the BPCIA and Accord stipulated to a preliminary injunction effective until October 1, 2025, Accord has not begun marketing its competing product and discovery regarding Accord's marketing or launch plans and other like topics identified by Amgen is not appropriate. To the extent Amgen will contend that objective indicia of nonobviousness support any contention of validity of any of the patents in suit, discovery regarding Amgen's products, manufacturing, and marketing may also be necessary.

b. Should discovery be conducted in phases or be limited to particular issues? Explain.

The parties agree that the parties should focus on initial targeted discovery to allow Amgen to narrow and focus the case promptly for the benefit of all parties and the Court, as set forth in the parties' proposed case schedules (MDL ECF No. 21, Ex. B). In particular, Amgen needs to obtain prompt discovery of technical information relating to Accord's proposed biosimilar products and its manufacturing of those products, which will allow Amgen to focus its infringement contentions. In this regard, Accord has advised Amgen that it must seek discovery from Accord's suppliers pursuant to Rule 45 subpoena practice. (Dkt. 21 at PageID: 141.)

c. Proposed Schedule

1) Fed. R. Civ. P. 26 Disclosures.

As set forth in Section 5, *supra*, the parties will exchange initial disclosures under Fed. R. Civ. P. 26(a)(1) on the date when Amgen must serve its L. Pat. R. 3.1 infringement contentions, as set forth by the Court's case schedule.

2) E-Discovery conference pursuant to L. Civ. R. 26.1(d).

As set forth in Section 11, *infra*, the parties will continue to confer regarding E-discovery and either submit a Stipulation Regarding Discovery of Electronically Stored Information or present any issues for resolution by the Court.

3) Service of initial written discovery.

As set forth in Section 8, *supra*, Amgen and Accord have already served initial written discovery on each other.

4) Maximum of written discovery requests by each party to each other party.

Collectively, Amgen may serve 25 requests for admission (exclusive of requests directed at authenticating documents) on Accord. Collectively, Accord may serve 25 requests for

admission (exclusive of requests directed at authenticating documents) on Amgen.

Amgen's Position: Collectively, Amgen may serve 40 interrogatories on Accord. Collectively, Accord may serve 40 interrogatories on Amgen. *See Amgen v. Samsung*, No. 1:24-cv-08417-CPO-EAP (D.N.J.), ECF No. 93, ¶ 2(c) (ordering 40 interrogatories per side).

Accord's Position: Collectively, Amgen may serve 25 interrogatories on Accord. Collectively, Accord may serve 25 interrogatories on Amgen, as directed by Fed. R. Civ. P. 33.

Agreed Position: To the extent a party seeks leave to serve additional requests for admission and/or interrogatories, that party may do so with consent of the other party or may make an application to the Court.

Amgen and Accord agree there should be no limits on requests for production.

5) Maximum of depositions to be taken by each party.

Depositions of persons in their individual capacity include, but are not necessarily limited to, depositions taken pursuant to Fed. R. Civ. P. 30(b)(1), Fed. R. Civ. P. 45, or under any Hague Convention procedures or letters rogatory.

A deposition should be limited to seven (7) hours of testimony per witness. Counsel for Amgen and Accord agree that they will cooperate in the scheduling of party depositions and make reasonable efforts to schedule such depositions within the calendar period requested by the party taking the deposition negotiating in good faith to consider the time zone of the witness and the time zone of counsel if being taken remotely.

Amgen's Position: Below, Accord suggests text requiring that depositions be conducted remotely. While Amgen may agree to take some depositions remotely, there is no basis in the Rules or case law to require remote depositions.

Accord's Position: The parties will work together cooperatively in good faith to negotiate

the means, time, and location of depositions of witnesses outside of the United States to minimize inconvenience to witnesses and undertake such depositions remotely.

Agreed Position: If a person is designated under Fed. R. Civ. P. 30(b)(6) to address more than 10 topics, the parties shall cooperate to make the witness available for additional time sufficient to cover any additional designated topics.

Counsel for Amgen and Accord agree to accept service by email of deposition notices for the parties and current employees of the parties. Acceptance of deposition notices or subpoenas by counsel does not waive any defense other than objections to service.

Amgen may collectively take 100 total hours of depositions of no more than 15 total persons in their individual capacity and/or under Fed. R. Civ. P. 30(b)(6). Accord may collectively take 100 total hours of depositions of no more than 15 total persons in their individual capacity and/or under Fed. R. Civ. P. 30(b)(6). To the extent a party seeks leave for additional deposition time and/or witnesses, that party may make an application to the Court.

The parties do not anticipate producing or taking the testimony of any foreign language witnesses in this case. For any deposition of a witness who testifies substantially with the assistance of an interpreter, only half of the time of such depositions shall be counted against a party's totals and, as a result, depositions where an interpreter is used substantially may be conducted over the course of multiple days.

Counsel taking the deposition of any foreign witness will be responsible for providing an interpreter, and Counsel for the deposed foreign witness may also retain a separate interpreter.

6) Motions to amend or to add parties to be filed by _____,

For the reasons set forth in Section 9.g, *infra*, regarding the need for a phased claim construction process, the parties submit that it is premature at this time to set deadlines for

motions to amend or add parties, and that the parties and the Court should address the remainder of the schedule after the initial claim construction process is complete or nearing completion.

7) **Factual discovery to be completed by: *see* MDL ECF No. 29** (entered Scheduling Order)

8) **Plaintiffs' expert reports due on *see* MDL ECF No. 29** (entered Scheduling Order)

9) **Defendants' expert reports due on *see* MDL ECF No. 29** (entered Scheduling Order)

10) **Expert depositions to be completed by *see* MDL ECF No. 29** (entered Scheduling Order)

11) **Dispositive motions to be filed by *see* MDL ECF No. 29** (entered Scheduling Order)

d. Set forth any special discovery mechanism or procedure requested.

Protocols for Service by Email

Amgen and Accord agree that service by electronic means shall be allowed as set forth in Fed. R. Civ. P. 5(b)(2)(E) and that such service shall be complete upon transmission, provided that the sender does not receive any indication that such electronic transmission was unsuccessful. Service by electronic means shall be considered the same as hand delivery for purposes of calculating the time to respond. Documents served on Amgen shall be sent to the following email addresses: AmgenDmab@sidley.com; DMAB-Accord@mintz.com; walsh-dmab-amgen@walsh.law. Documents served on Accord shall be sent to the following email addresses: amenchaca@mcandrews-ip.com; Accord-DEN@mcandrews-ip.com.

e. A pretrial conference may take place on _____.

For the reasons set forth in Section 9.g, *infra*, regarding the need for a phased claim

construction process, the parties submit that it is premature at this time to set a date for a pretrial conference, and that the parties and the Court should address the remainder of the schedule after the initial claim construction process is complete or nearing completion.

f. A trial has not been set by this Court.

For the reasons set forth in Section 9.g, *infra*, regarding the need for a phased claim construction process, the parties submit that it is premature at this time to set a date for trial, and that the parties and the Court should address the remainder of the schedule after the initial claim construction process is complete or nearing completion.

g. The scope and timing of any claim construction discovery including disclosure of and discovery from any expert witness permitted by the court (L. Pat. R. 2.1(a)(2)):

The parties agree that claim construction should occur in two phases. In the first phase of claim construction, the parties agree that the *Accord* case be put on a schedule that would allow Accord to participate in *Samsung* claim construction proceedings on any patents that overlap with the patents still at issue in the *Samsung* case (the narrowed patents as of the start of claim construction in the *Samsung* case, which corresponds to the first phase of claim construction in this case). In the second phase, the parties in *Accord* would proceed through claim construction on patents that do not overlap with those in the claim construction proceedings in *Samsung*. MDL ECF No. 29 (entered Scheduling Order).

h. The format of the claim construction hearing, including whether the Court will hear live testimony, the order or presentation, and the estimated length of the hearing (L. Pat. R. 2.1(a)(3)):

Amgen and Accord believe it is premature at this time to determine whether the Court should hear live testimony and the estimated length of the hearing, though Amgen's position is that Amgen should present first at the hearing.

i. How the parties intend to educate the Court on the patent(s) at issue (L. Pat. R.

2.1(a)(4)):

The parties agree that a tutorial will be required for the Court to gain familiarity with the technology involved in the patents asserted in this litigation. MDL ECF No. 29 (entered Scheduling Order with tutorial dates).

10. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problems with out-of-state witnesses and documents, etc.)?

Amgen and Accord anticipate utilizing videotaped depositions.

The parties do not anticipate the production of foreign language documents in this case. Any foreign language documents produced in response to a request for production must be produced no later than 30 days in advance of the close of fact discovery, in order to allow time for translations and review. The producing party shall produce English translations of any foreign language documents that are kept in the ordinary course of business.

Although the parties expect that there will be foreign witnesses located abroad, in India in particular, the parties do not anticipate producing or taking the testimony of any foreign language witnesses in this case that would require the use of interpreters.

Amgen and Accord agree that no laws of foreign countries preclude, prohibit, and/or impede either party from producing documents and information in this case consistent with the Federal Rules of Civil Procedure, the Local Patent Rules, and the Court's procedures. Amgen and Accord also agree that, while the laws of certain foreign countries restrict the locations where a deposition may occur, no laws of foreign countries preclude, prohibit, and/or impede either party from producing witnesses for deposition in this case in countries that allow depositions to occur.

11. Do you anticipate any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced? Yes ___ No __X__. If so, how will electronic discovery or data be disclosed or produced? Describe any agreements

reached by the parties regarding same, including costs of discovery, production, related software, licensing agreements, etc.

Amgen and Accord will negotiate provisions for the handling and production of electronically stored information, and will thereafter either submit a Stipulation Regarding Discovery of Electronically Stored Information or present any issues for resolution by the Court.

12. Do you anticipate entry of a Discovery Confidentiality Order? See L. Civ. R. 5.3(b) and Appendix S.

A stipulated Confidentiality Order ("DCO") was entered by the Court on March 27, 2025. MDL ECF No. 15. In addition, the Court has ordered the parties to confer regarding a confidentiality protocol in this multidistrict litigation to be submitted to the Court no later than April 16, 2025. MDL ECF Nos. 17 ¶ 4 & 18 ¶ 4.

13. Do you anticipate any discovery problem(s) not listed above? Yes __ No __X__

14. State whether this case is appropriate for voluntary arbitration (pursuant to Local Civil Rule 201.1 or otherwise) or mediation (pursuant to Local Civil Rule 301.1 or otherwise). If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition or dispositive motions, etc.).

Amgen and Accord believe this case is appropriate for mediation.

15. Is this case appropriate for bifurcation? Yes ____ No _____

Amgen believes it is premature at this time to determine if this case is appropriate for bifurcation. Accord does not believe this case is appropriate for bifurcation.

16. An interim status/settlement conference (with clients in attendance) should be held in _____.

The Court has ordered monthly in-person status conferences in this case to be held on the first Tuesday of each month in MDL ECF No. 17 ¶ 3. Accord intends to seek permission to attend remotely.

17. The parties do not consent to the trial being conducted by a Magistrate Judge.

18. Identify any other issues to be addressed at the Rule 16 Scheduling Conference.

N/A.

Dated: April 21, 2025

/s/ Liza M. Walsh

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EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF
PENNSYLVANIA

IN RE: SOCLEAN, INC., MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION **This Document Relates to:** ***All Consumer Cases***	Master Docket: Misc. No. 22-mc-152 MDL No. 3021

PRETRIAL ORDER #26

REGARDING DEADLINES AND LIMITS OF WRITTEN DISCOVERY

Per Pretrial Order #14 [Doc. 118], the Parties set forth the following limits with regard to written discovery.

1. **Requests for Production.** Consumer Plaintiffs have propounded two sets of Requests for Production (RFPs) on Defendant SoClean, Inc. The requests made thus far total sixty-nine. SoClean has provided some responsive documents to the first set of RFPs and the Parties continue to work cooperatively to identify deficiencies and facilitate the exchange of requests and documents.

   a) Both Consumer Plaintiffs and Defendant SoClean will each be allowed to make **250** total Requests for Production.

   b) By **May 1, 2023**, document productions will be substantially complete.

2. **Interrogatories.**

   a) Both Consumer Plaintiffs and Defendant SoClean will each be allowed **50** total interrogatories, including all discrete subparts, directed at each Party. Each individual consumer Plaintiff is considered a separate Party for purposes of this Stipulation.

b) Interrogatories will be answered within thirty (30) days of receipt of the requests, per Fed. R. Civ. P. 33(b)(2).

3. **Requests for Admission.**

a) Both Consumer Plaintiffs and Defendant SoClean will each be allowed **150** total Requests for Admission under Fed. R. Civ. P. 36(a)(1)(A).

b) Consumer Plaintiffs and Defendant SoClean will not be limited in the number of Requests for Admission under Fed. R. Civ. P. 36(a)(1)(B).

c) Each request shall seek a discrete, singular admission and shall not be compound or include subparts.

d) Federal Civil Rule of Procedure 36(a)(3) will govern the time to respond and the effect of not responding.

4. This Addendum does not waive the Parties' rights to stipulate to or request revision of these limits if additional discovery is required.

IT IS SO ORDERED.

Dated: 9/21/2022

/s/ JOY FLOWERS CONTI

Joy Flowers Conti
Senior United States District Judge

SO STIPULATED AND AGREED.

DATED: September 16, 2022

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EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: XARELTO (RIVAROXABAN) ('310) PATENT LITIGATION	)	MDL NO. 21-MD-3017 (RGA)
BAYER PHARMA AG, BAYER AG and JANSSEN PHARMACEUTICALS, INC., Plaintiffs,	)	
v.	)	C.A. No. 22-165 (RGA)
MICRO LABS LTD. and MICRO LABS USA INC., Defendants.	)	

~~[PROPOSED]~~ SCHEDULING ORDER

This 22 day of March, 2022, the Court having waived an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b),[1] and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS ORDERED that:

1. Consolidation. Civil Action No. 22-165-RGA is consolidated for all purposes, including trial, with the actions previously consolidated into Civil Action No. 21-314-RGA, and all papers shall be filed in Civil Action No. 21-314-RGA.

[1] This Order follows substantially similar scheduling orders entered in the following related actions involving the same products and patents: (1) Order dated October 27, 2021, in related actions C.A. Nos. 21-314-RGA, 21-732-RGA, 21-1000-RGA, and 21-1001-RGA; and (2) Order dated January 31, 2022, in related action C.A. 21-1742-RGA. The parties have agreed that substantially the same schedule in the related actions should apply in this action. This Order thus provides for substantially similar due dates as the scheduling orders in the related actions, but has been adjusted to account for due dates that have already passed or are soon to pass.

2. Rule 26(a)(1) Initial Disclosures. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) within 10 business days of the date of this Order.

3. Joinder of Other Parties and Amendment of Pleadings. All motions to amend or supplement pleadings shall be filed on or before July 1, 2022; and motions to join other parties shall be filed on or before August 5, 2022.

4. Discovery.

a. Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before October 28, 2022.

b. Document Production. Document production shall be substantially complete by August 5, 2022.

c. Requests for Admission. The Plaintiff Groups[2] will coordinate with one another and may jointly serve up to **25** requests for admission on each Defendant Group.[3] The Defendant Groups will coordinate with one another and may jointly serve up to **25** requests for admission on each Plaintiff Group. In addition, each Defendant Group may serve on each Plaintiff Group up to **5** individualized requests for admission, and each Plaintiff Group may serve on each Defendant Group up to **5** individualized requests for admission. Any additional requests for admission may only be served by agreement of the parties or with leave of Court. Any requests

[2] The Plaintiff Groups in this action are: (1) Bayer Pharma AG and Bayer AG; and (2) Janssen Pharmaceuticals, Inc.

[3] The Defendant Groups in this action are: (1) Lupin Limited and Lupin Pharmaceuticals, Inc.; (2) Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.; (3) Taro Pharmaceuticals Industries, Ltd. and Taro Pharmaceuticals U.S.A., Inc.; (4) Teva Pharmaceuticals USA, Inc.; (5) Mylan Pharmaceuticals Inc. and Mylan Inc.; and (6) Micro Labs Ltd. and Micro Labs USA Inc.

for admission directed to the authentication or admissibility of documents are excluded from the limitations above. The parties will work to agree on authentication where possible.

d. Interrogatories. The Plaintiff Groups will coordinate with one another and may jointly serve up to **25** interrogatories on each Defendant Group. All Defendant Groups will coordinate with one another and may jointly serve up to **25** interrogatories on each Plaintiff Group. In addition, each Defendant Group may serve on each Plaintiff Group up to **5** individualized interrogatories, and each Plaintiff Group may serve on each Defendant Group up to **5** individualized interrogatories. Any additional interrogatories may only be served by agreement of the parties or with leave of Court.

e. Depositions.

i. Limitation on Hours for Deposition Discovery. The Plaintiff Groups collectively are limited to a total of 30 hours of taking testimony by deposition upon oral examination of each Defendant Group, excluding experts. The Defendant Groups collectively are limited to a total of 70 hours of taking testimony by deposition upon oral examination, excluding experts. Any deposition lasting less than 5 hours will count as 5 hours against the total time of the side taking the deposition. If a deponent testifies wholly or substantially through an interpreter, the party taking the deposition shall be permitted, on a pro rata basis, 1.5 hours of deposition time for each hour spent testifying through the interpreter. The provisions of Federal Rule of Civil Procedure 30(d)(l) shall apply.

ii. Location of Depositions. The parties shall meet and confer regarding the locations of depositions, taking into account the worldwide health situation and the convenience of the deponent. The parties may agree to take remote depositions.

f. Discovery Matters and Disputes Relating to Protective Orders. Should counsel find they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Case Manager to schedule an in-person conference/argument. Unless otherwise ordered, by no later than seven business days prior to the conference/argument, any party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. By no later than five business days prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's opposition. A party should include with its letter a proposed order with a detailed issue-by-issue ruling such that, should the Court agree with the party on a particular issue, the Court could sign the proposed order as to that issue, and the opposing party would be able to understand what it needs to do, and by when, to comply with the Court's order. Any proposed order shall be e-mailed, in Word format, simultaneously with filing to rga_civil@ded.uscourts.gov.

If a discovery-related motion is filed without leave of the Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery matters procedures set forth in this Order.

g. Miscellaneous Discovery Matters.

i. Initial Disclosures

i. Each Plaintiff Group shall make its disclosures under Paragraph 4(a) of the Default Standard no later than 10 days from the date of this Order.

ii. Micro Labs Ltd. and Micro Labs USA, Inc. (collectively, "Micro Labs") shall produce its core technical documents under Paragraph

4(b) of the Default Standard, including a complete copy of Micro Labs's ANDA, no later than 15 days after service of Plaintiffs' Paragraph 4(a) disclosures. In addition, the parties shall make their disclosures under Paragraph 3 of the Default Standard on the same date;

iii. Each Plaintiff Group shall make its disclosures under Paragraph 4(c) of the Default Standard no later than 15 days after service of Defendants' Paragraph 4(b) disclosures; and

iv. Micro Labs shall make its disclosures under Paragraph 4(d) of the Default Standard no later than 15 days after service of Plaintiffs' Paragraph 4(c) disclosures.

ii. There is pending litigation in the Northern District of West Virginia involving the patent-in-suit, U.S. Patent No. 10,828,310 ("the '310 patent"). *See Bayer Pharma AG et al. v. Mylan Pharmaceuticals Inc. and Mylan Inc.*, 21-cv-99-TSK (N.D. W. Va.). That case has been transferred to this Court for coordinated or consolidated pretrial proceedings. C.A. No. 21-1742-RGA, D.I. 68. Plaintiffs will consider filing further litigation involving the '310 patent depending on future events, including should a generic manufacturer provide a notice letter stating an intent to seek approval to market a generic version of XARELTO® 2.5 mg tablets prior to expiration of the '310 patent.

iii. Mylan Pharmaceuticals Inc. filed a Petition for *Inter Partes* Review with respect to the '310 patent on February 2, 2022. The Patent Owner

Preliminary Response to the Petition is due May 11, 2022.

iv. By September 9, 2022, Plaintiffs shall reduce the number of claims they intend to assert at trial to no more than four. By September 30, 2022, Defendants shall identify no more than six references that they intend to rely upon for any anticipation and/or obviousness defenses and, to the extent Defendants intend to rely upon a combination of references for obviousness purposes, identify no more than three such combinations.

5. Application to Court for Protective Order. The parties agree to use the Protective Order entered by the Court in Case No. 21-314-RGA,[4] which contained the following paragraph:

> Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

6. Papers Filed Under Seal. When filing papers under seal, counsel shall deliver to the Clerk the required number of copies as directed in paragraph 7. A redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.

7. Courtesy Copies. The parties shall provide to the Court two courtesy copies of all briefs and one courtesy copy of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal.

[4] Plaintiffs and Micro Labs adopt the Protective Order in the consolidated action (C.A. No. 21-314-RGA), and Micro Labs is deemed a signatory for all intents and purposes retroactive to the date of entry, including for purposes of expert disclosures already made by Plaintiffs under the Protective Order.

8. Claim Construction Issue Identification. On or before April 29, 2022, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than May 13, 2022. The Joint Claim Construction Chart, in Word format shall be e-mailed simultaneously with filing to rga_civil@ded.uscourts.gov. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

9. Claim Construction Briefing[5]. Plaintiffs shall serve, but not file, their opening brief, not to exceed 5,000 words, on June 3, 2022. Defendants shall serve, but not file, their answering brief, not to exceed 7,500 words, on June 24, 2022. Plaintiffs shall serve, but not file, their reply brief, not to exceed 5,000 words, on July 15, 2022. Defendant shall serve, but not file their sur-reply brief, not to exceed 2,500 words, on July 29, 2022. No later than August 5, 2022, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled

[5] As each brief is written and provided to the opposing party, the individual responsible for verifying the word count will represent to the other party that it has so verified and by what means. These verifications should not be provided to the Court unless a dispute arises about them. Pictures, Figures copied from the patent, and other illustrations do not count against the word limit. Plaintiffs should include with its opening brief one or more representative claims with the disputed terms italicized. Should Defendants want to add additional representative claims, Defendants may do so. The representative claims and the agreed-upon claim constructions do not count against the word limits.

briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

I. Representative Claims

II. Agreed-upon Constructions

III. Disputed Constructions

A. [TERM 1][6]

1. Plaintiffs' Opening Position
2. Defendants' Answering Position
3. Plaintiffs' Reply Position
4. Defendants' Sur-Reply Position

B. [TERM 2]

1. Plaintiffs' Opening Position
2. Defendants' Answering Position
3. Plaintiffs' Reply Position
4. Defendants' Sur-Reply Position

Etc. The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an appendix, the parties shall submit them in a Joint Appendix.

10. Hearing on Claim Construction. Beginning at 9:00 a.m. on August 23, 2022, the Court will hear argument on claim construction. Absent prior approval of the Court (which, if it is sought, must be done so by joint letter submission no later than the date on which answering claim construction briefs are due), the parties shall not present testimony at the argument, and the argument shall not exceed a total of three hours. When the Joint Claim Construction Brief is filed, the parties shall simultaneously file a motion requesting the above-scheduled claim construction

[6] For each term in dispute, there should be a table or the like setting forth the term in dispute and the parties' competing constructions. The table does not count against the word limits.

hearing, state that the briefing is complete, and state how much total time the parties are requesting that the Court should allow for the argument.

11. Disclosure of Expert Testimony.

a. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before November 18, 2022. Plaintiffs' responsive reports, including Plaintiffs' expert reports regarding objective indicia of nonobviousness, and Defendants' responsive reports are due on or before January 13, 2023. Reply expert reports limited to Defendants' responses on objective indicia of nonobviousness are due on or before, February 10, 2023. No other expert reports will be permitted without either the consent of all parties or leave of the Court. If any party believes that an expert report does not comply with the rules relating to timely disclosure or exceeds the scope of what is permitted in that expert report, the complaining party must notify the offending party within one week of the submission of the expert report. The parties are expected to promptly try to resolve any such disputes, and, when they cannot reasonably be resolved, use the Court's Discovery Dispute Procedure or the complaint will be waived.

By February 17, 2023, the parties shall advise of the dates and times of their experts' availability for deposition. Depositions of experts shall be completed on or before April 7, 2023.

b. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than April 14, 2023, unless otherwise ordered by the Court.

12. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

13. Case Dispositive Motions. No. case dispositive motions shall be filed without leave of Court.

14. Pretrial Conference. On May 19, 2023, the Court will hold a Rule 16(e) final pretrial conference in Court with counsel beginning at 8:30 a.m. The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5 p.m. on the fourth business day before the date of the final pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.

15. Motions *in Limine*. Motions *in limine* shall be separately filed, with each motion containing all the argument described below in one filing for each motion. Any supporting documents in connection with a motion *in limine* shall be filed in one filing separate from the motion *in limine*. Each party shall be limited to three *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three pages of argument and may be opposed by a maximum of three pages of argument, and the party making the *in limine* request may add a maximum of one additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three-page submission (and, if the moving party, a single one-page reply). No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

16. Trial. This matter is scheduled for a two-day bench trial on invalidity arguments, with an additional half-day bench trial for each Defendant Group's non-infringement arguments to the extent non-infringement issues remain[7] with trial days from 8:30 am to 5:00 pm beginning on May 30, 2023. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

UNITED STATES DISTRICT JUDGE

[7] At this early stage in the case, Defendants think it prudent to reserve time for each Defendant Group to present non-infringement positions because Defendants are not in a position to ascertain how distinct each Defendant Group's non-infringement positions are from each other. Should the Court prefer, we propose the Court conduct a status conference one month prior to the pretrial conference to discuss the order and timing of trial.

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	C.A. No. 20-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ALKEM LABORATORIES LTD., AUROBINDO PHARMA USA INC., AUROBINDO PHARMA LTD., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT III, LAURUS LABS LIMITED, LAURUS GENERICS INC., MACLEODS PHARMACEUTICALS LTD., MACLEODS PHARMA USA, INC., TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., Defendants.	C.A. No. 21-1330-RGA

SCHEDULING ORDER

This 29 day of August, 2022, the Court having consulted with the parties' attorneys and received a joint proposed scheduling order pursuant to Local Rule 16.2(a) and the parties having

determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;[1,2]

IT IS HEREBY ORDERED that:

1. Initial Disclosures

a. Rule 26(a)(l) Initial Disclosures. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(l) and Paragraph 3 of the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("Del. Default Standard") within **five** (**5**) business days of the date of this Order.

b. Production of File History for Asserted Patent. Within five (5) business days of the entry of this order, Plaintiff shall produce the file history for the asserted patent.

c. Initial Infringement Claim Charts. On Aug. 6, 2021, Plaintiff produced claim charts relating each Defendant Group's accused products, and/or the uses thereof, to the asserted patent claims of the '918 patent each Defendant Group[3] allegedly infringes. Plaintiff

[1] For the Court's convenience, the parties attach, as Exhibit A, a chart setting forth the proposed schedule for the case.

[2] U.S. Patent No. 11,096,918 is asserted against all Defendant Groups (as defined below), including Hetero and Torrent. However, in the '918 patent cases against Hetero and Torrent, Defendants Hetero and Torrent asserted counterclaims against U.S. Patent Nos. 9,517,226, 9,937,143, and 11,135,192. Novartis filed a motion to dismiss these counterclaims. The parties completed the briefing on the motion which awaits oral argument and/or resolution. Plaintiff and Hetero and Torrent will comply with the deadlines set forth in this Order with respect to the '226, '143, and '192 patents. Should the Court deny Plaintiff's motion to dismiss Hetero's counterclaims, Hetero will ask the court to sever its counterclaims from the present case and transfer them to C.A. No. 21-1760-RGA. Should the Court deny Plaintiff's motion to dismiss Torrent's counterclaims, Torrent will ask the Court to sever its counterclaims from the present case and transfer them to C.A. No. 21-1794-RGA. Plaintiff does not believe its motions to dismiss should be denied.

[3] "Defendant Group" herein shall mean a group of Defendants, each of which comprises a sacubitril/valsartan ANDA-filing entity and its related entities, if any. In this litigation there

has supplemented those initial claim charts on July 22, 2022. Within **thirty** (**30**) days of the entry date of this order, Plaintiff shall produce to Defendants Hetero and Torrent an initial patent claim chart relating those Defendants' accused products, and/or the uses thereof, to the asserted patent claims of U.S. Patent Nos. 11,135,192, 9,937,143, and 9,517,226 that those Defendants allegedly infringe.

d. Initial Invalidity Contentions. By Sept. 9, 2022, Defendants collectively shall serve on Plaintiff their initial invalidity contentions for each asserted claim of the '918 patent, as well as all of the references (*e.g.*, publications and patents) cited therein. Within **sixty** (**60**) days of the entry date of this order, Defendants Hetero and Torrent shall collectively serve on Plaintiff their initial invalidity contentions for each asserted claim of U.S. Patent Nos. 11,135,192, 9,937,143, and 9,517,226, as well as all of the references (*e.g.*, publications and patents) cited therein.

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currently are 6 Defendant Groups, as listed below. The '918 patent case against Alkem Laboratories Ltd. has been stayed.

(1) Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. (collectively "Aurobindo");

(2) Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively "Dr. Reddy's");

(3) Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III (collectively "Hetero");

(4) Laurus Labs Limited and Laurus Generics Inc. (collectively "Laurus");

(5) Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively "Macleods"); and

(6) Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively "Torrent").

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before Jan. 5, 2023.

3. Discovery.

a. Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before June 16, 2023.

b. Prior Discovery. Any discovery previously given or taken in C.A. No. 20-md-2930 and its underlying civil actions shall be treated as if it were given or taken in the above-captioned cases and need not be re-produced in these or any further actions involving any Defendants' ANDAs. To the extent there is overlap between this Action and the related actions involving U.S. Patent No. 11,058,667,[4] the Parties agree to endeavor to avoid duplicative discovery; however, the limits on discovery set forth in the scheduling orders for this Action and the related actions shall remain unchanged. For the avoidance of doubt, any discovery in the related actions involving U.S. Patent No. 11,058,667 may be used in this Action and *vice versa*.

c. Production of Core Technical Documents. Within five (5) business days of the entry date of this order, Defendants shall produce any amendments, supplements, or other updates to their Abbreviated New Drug Applications ("ANDAs"), and any correspondence related thereto to or from the United States Food and Drug Administration ("FDA"), to the extent not already produced in C.A. No. 20-md-2930 and its underlying civil actions.

d. Document Production. Document production shall be substantially complete by Dec. 14, 2022, for all requests for production served at least three (3) months before the deadline for substantially completing document production. Supplemental productions shall

[4] *See*, C.A. Nos. 22-32-RGA (stayed), 21-1407-RGA, 21-1452-RGA, 22-498-RGA, 21-1760-RGA, 22-186-RGA, 22-451-RGA, 22-83-RGA (stayed), 21-1794-RGA, 22-440-RGA, 22-726-RGA.

be permitted after the deadline in this paragraph for requests for production served after or less than three months before the deadline for substantial completion of document production.

e. Requests for Admission. Plaintiff may serve up to **fifty (50)** Requests for Admission on each Defendant Group, not including admissions directed toward admissibility including authentication of documents. Defendants collectively may serve up to **twenty-five (25)** common Requests for Admission on Plaintiff, not including admissions directed toward admissibility including authentication of documents. Each Defendant Group may serve an additional **ten (10)** nonduplicative requests for admission on Plaintiff directed solely to issues specific to that Defendant Group, not including admissions directed toward admissibility including authentication of documents. There is no limit on the number of reasonable requests for admission the parties may serve to establish the authenticity of documents or establish documents as business records. Requests for admission directed to document authentication or establishment of business records shall be clearly denoted as such, and shall be served separately from any requests for admission subject to the numerical limitations stated above. Such requests directed to document authentication or establishment of business records can be served at any time prior to trial and the parties agree to work in good faith to stipulate in advance of trial to the authenticity and admissibility of the key documents upon which they intend to rely at trial. Defendants shall work in good faith to coordinate and serve on Plaintiff common requests for admission directed to document authentication or establishment of business records.

f. Common Discovery. The parties shall coordinate activities to reduce duplicative and cumulative discovery that is common to all Defendants ("Common Discovery Issues"). Common Discovery Issues include, but are not limited to, the validity of the patent-in-suit.

g. Requests for Production. The parties will make a good faith effort to coordinate and serve common requests for production (*i.e.*, Defendants shall use best efforts to serve common requests for production on common factual issues, including on issues of validity, and Plaintiff shall use best efforts to serve common requests on the Defendants or subsets of Defendants on common factual issues). Nothing in this section shall prevent a party from serving an individual request for production, or two or more, but less than all, Defendants from serving a joint request for production. For the avoidance of doubt, if two or more, but less than all, Defendant Groups serve a joint request for production on an issue of validity, such Defendant Groups shall do so together, as part of Defendants' good faith effort to coordinate on requests for production.

h. Production of Samples. Each Defendant Group shall produce samples of its accused products, active ingredients, and excipients, in reasonable amounts at a time and in a manner agreed to by the parties, provided however, that samples of accused products, active ingredients, and excipients shall be produced no later than five (5) months before the proposed expiration dates, to the extent that any such unexpired samples are available.

i. Interrogatories.

Plaintiff may serve **twenty-five (25)** Interrogatories (including all discrete subparts) on each Defendant Group. Collectively, Defendants may serve a maximum of **fifteen (15)** common Interrogatories (including all discrete subparts) on Plaintiff. Each Defendant Group may serve up to **ten (10)** additional, non-duplicative Interrogatories (including all discrete subparts) on Plaintiff, provided that, for issues of validity Defendants use their best efforts to serve jointly any Interrogatories common to two or more, but less than all, Defendant Groups. For the avoidance of doubt, if two or more, but less than all, Defendant Groups serve a joint Interrogatory on an

issue of validity, such Defendant Groups shall do so together, to the extent possible, as part of a good faith effort to avoid duplicative individual Interrogatories relating to validity. Such joint Interrogatories will count against the individual Interrogatory limit of each Defendant Group serving such joint Interrogatories and will not count against Defendants' common Interrogatories limit.

j. Depositions.

i. Limitation on Hours for Deposition Discovery.

Absent an agreement between the parties to the contrary or unless permitted by the Court following a showing of good cause, Plaintiff may take a maximum of **four (4)** fact depositions from each Defendant Group. Defendants collectively may take the depositions of the named inventors and up to **five** (**5**) additional fact depositions from Plaintiff. Defendants shall use best efforts to coordinate to avoid duplicative questioning. Each fact witness may be deposed only once absent a showing of good cause. The deposition of a single person in both the person's personal capacity and as a 30(b)(6) designee shall count as a single deposition. The Parties agree they will endeavor to coordinate depositions of fact witness between this Action and the related actions involving U.S. Patent No. 11,058,667[5] in an effort to avoid multiple depositions of the same fact witness between these two cases; however, the limits on depositions set forth in this paragraph and in the scheduling order for the related actions shall remain unchanged.

For purposes of the deposition limits, a single 30(b)(6) deposition notice will count as one deposition regardless of how many individuals a party designates to respond to the notice, provided however, that Plaintiff may take a maximum of eight (8) hours of 30(b)(6) deposition

[5] *See*, C.A. Nos. 22-32-RGA (stayed), 21-1407-RGA, 21-1452-RGA, 22-498-RGA, 21-1760-RGA, 22-186-RGA, 22-451-RGA, 22-83-RGA (stayed), 21-1794-RGA, 22-440-RGA, 22-726-RGA.

testimony from each Defendant Group and Defendants collectively may take a maximum of thirteen and one half (13.5) hours of 30(b)(6) deposition testimony from Plaintiff. If an individual is deposed in both the person's personal capacity and as a 30(b)(6) designee, the examining attorney shall clearly state on the record when the individual is being asked questions in his or her capacity as a 30(b)(6) designee.

The number of depositions above apply to depositions of a party's officers, directors, current employees, former employees, corporate affiliates, and API supplier(s) or drug product manufacturer of a party to the extent such officers, directors, current employees, former employees, corporate affiliates, and API supplier(s) or drug product manufacturer of a party agree to accept service of and respond to requests for production without requiring formal third-party discovery procedures. Except as expressly provided above, the deposition limits above do not apply to depositions of other third-party witnesses. Nothing contained in this section pertaining to former employees, corporate affiliates, third-party contractual affiliates, or API supplier(s) of a party shall be construed as a party consenting to a deposition of said former employee, corporate affiliate, third-party contractual affiliate, or API supplier(s) or an agreement to accept notice of deposition on behalf of said former employee, corporate affiliate, third-party contractual affiliate, or API supplier(s).

Each fact deposition is limited to a maximum of **seven** (**7**) hours total deposition time for fact deponents, unless extended by agreement of the parties or leave of the Court.

The time limits in this section apply regardless of whether the witness is being deposed in an individual capacity, as a 30(b)(6) designee, or both. For any deposition occurring in a non-English language and requiring an interpreter, two (2) hours of time on the record will count for one (1) hour of deposition time.

The parties agree that deposition testimony taken in C.A. No. 20-md-2930-RGA may be used in the instant case.

ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court or by agreement of the parties. A defendant who becomes a cross-claimant or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision. Should the parties agree that the deposition of a witness may proceed remotely, the attorneys will cooperate to determine a reasonable starting time for the deposition. The parties here further agree to confer in good faith regarding the location of deposing witnesses located in foreign countries, including whether such deposition may proceed remotely.

k. Discovery Matters and Disputes Relating to Protective Orders. The parties agree to abide by the terms of the Stipulated Protective Order entered in 20-md-2930-(RGA) lead action (D.I. 80, so ordered 09/18/2020). Should counsel find they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Case Manager to schedule an in-person conference/argument. Unless otherwise ordered, by no later than seven (7) business days prior to the conference/argument, any party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. By no later than five (5) business days prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's opposition. A party should include with its letter a proposed order with a detailed issue-by-issue ruling such

that, should the Court agree with the party on a particular issue, the Court could sign the proposed order as to that issue, and the opposing party would be able to understand what it needs to do, and by when, to comply with the Court's order. Any proposed order shall be e-mailed, in Word format, simultaneously with filing to rga_civil@ded.uscourts.gov.

If a discovery-related motion is filed without leave of the Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery matters procedures set forth in this Order.

l. Bifurcation of Non-Liability Issues. Any issues other than liability, such as willfulness, exceptional case, attorneys' fees, damages and/or injunctive relief (including, for example, reliance on counsel's opinion and irreparable harm) shall be bifurcated for purposes of discovery and trial, unless good cause is shown otherwise. There are no damages issues at this time.

m. Miscellaneous Discovery Matters. There are no other pending or completed litigations, including IPRs, involving the asserted patent. Defendants should advise whether they expect to file one or more IPRs and, if so, when.

4. Application to Court for Protective Order. The parties agree that the Stipulated Protective Order entered in C.A. No. 20-md-2930-RGA (D.I. 80) applies to the instant case. The parties agree that any confidential information designated as "confidential" or "highly confidential" previously produced under that Protective Order in C.A. No. 20-md-2930-RGA or associated cases also may be used for the purpose of asserting, maintaining, monitoring, supervising, prosecuting, defending, or settling any claim in the instant case only in connection with the party that produced such information.

That protective order includes the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

5. Papers Filed Under Seal. When filing papers under seal, counsel shall deliver to the Clerk the required number of copies as directed in Paragraph 6. A redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

6. Courtesy Copies. The parties shall provide to the Court two (2) courtesy copies of all briefs and one courtesy copy of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal.

7. Claim Construction Issue Identification. On or before Nov. 4, 2022, Plaintiff ("a side") and all Defendants collectively (the other "side") shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s) along with the intrinsic and extrinsic evidence, if any, upon which it intends to rely with respect to each claim term/phrase. This document will not be filed with the Court. On Dec. 15, 2022, each side shall serve on the other side a chart setting forth each claim term/phrase with its rebuttal claim construction of those term(s)/phrase(s) and a list of the rebuttal intrinsic and extrinsic evidence, if any, upon which it intends to rely with respect to each claim term/phrase. Subsequent to exchanging that list, the sides will meet and confer no later than Dec. 22, 2022, to prepare a Joint Claim Construction Chart to be filed no later than Dec. 30, 2022. The Joint Claim Construction Chart, in Word format shall be e-mailed simultaneously with

filing to rga_civil@ded.uscourts.gov. The Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each side's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent at issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the sides shall not provide argument.

8. Claim Construction Briefing.[6] Plaintiff shall serve, but not file, its opening brief, not to exceed 5,000 words, on Jan. 20, 2023. Defendants collectively shall serve, but not file, their answering brief, not to exceed 7,500 words, on Feb. 10, 2023. Plaintiff shall serve, but not file, its reply brief, not to exceed 5,000 words, on Mar. 3, 2023. Defendants collectively shall serve, but not file their sur-reply brief, not to exceed 2,500 words, on Mar. 24, 2023. No later than Mar. 31, 2023, the sides shall file a Joint Claim Construction Brief. The sides shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

I. Representative Claims

II. Agreed-upon Constructions

III. Disputed Constructions

[6] As each brief is written and provided to the opposing party, the individual responsible for verifying the word count will represent to the other party that it has so verified and by what means. These verifications should not be provided to the Court unless a dispute arises about them. Pictures, Figures copied from the patent, and other illustrations do not count against the word limit. Plaintiff should include with its opening brief one or more representative claims with the disputed terms italicized. Should Defendants want to add additional representative claims, Defendants may do so. The representative claims and the agreed-upon claim constructions do not count against the word limits.

A. [TERM 1][7]

1. Plaintiff's Opening Position
2. Defendants' Answering Position
3. Plaintiff's Reply Position
4. Defendants' Sur-Reply Position

B. [TERM 2]

1. Plaintiff's Opening Position
2. Defendants' Answering Position
3. Plaintiff's Reply Position
4. Defendants' Sur-Reply Position

Etc. The sides need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an appendix, the sides shall submit them in a Joint Appendix.

9. Hearing on Claim Construction. Beginning at 9 a.m. on April 14, 2023, the Court will hear argument on claim construction. The Court will allow up to three (3) hours for argument on claim construction. Should the parties believe more than three (3) hours is needed for argument on claim construction, the parties shall submit a letter to the Court on Mar. 31, 2023, indicating additional time is requested. Absent prior approval of the Court (which, if it is sought, must be done so by joint letter submission no later than the date on which answering claim construction briefs are due), the sides shall not present testimony at the argument, and the argument shall not exceed a total of three hours. When the Joint Claim Construction Brief is filed, the sides shall simultaneously file a motion requesting the above scheduled claim construction hearing, state that the briefing is complete, and state how much total time each side is requesting that the Court should allow for the argument.

10. Disclosure of Expert Testimony.

[7] For each term in dispute, there should be a table or the like setting forth the term in dispute and the parties' competing constructions. The table does not count against the word limits.

a. Expert Reports. For the side who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before July 21, 2023. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another side including Plaintiff's opening disclosure regarding any objective indicia of non-obviousness is due on or before Sept. 1, 2023. Reply expert reports from the side with the initial burden of proof including Defendants' responsive disclosure regarding any objective indicia of non-obviousness are due on or before Oct. 27, 2023. Plaintiff's sur-reply expert reports on the issue of objective indicia of non-obviousness are due on or before Nov. 10, 2023. No other expert reports will be permitted without either the consent of all relevant parties or leave of the Court. If any party believes that an expert report does not comply with the rules relating to timely disclosure or exceeds the scope of what is permitted in that expert report, the complaining party must notify the offending party within one (1) week of the submission of the expert report. The parties are expected to promptly try to resolve any such disputes, and, when they cannot reasonably be resolved, use the Court's Discovery Dispute Procedure or the complaint will be waived.

Within one week after the service of reply expert reports, the parties shall advise of the dates and times of their experts' availability for deposition. Depositions of experts shall be completed on or before Dec. 22, 2023. The parties shall meet and confer after exchanging reply expert reports to agree on a reasonable amount of time for the deposition of any individual expert, for example, for any expert who has provided opinions on infringement that are common to more than one Defendant Group, or any expert who has provided opinions on both infringement and validity. If a dispute arises regarding the amount of time for depositions of any expert, the parties shall follow the discovery dispute procedure set forth in Paragraph 3(k).

b. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than Jan. 5, 2024, unless otherwise ordered by the Court. Oppositions to such motions shall be filed no later than Jan. 19, 2024, and replies to such motions shall be filed no later than Jan. 26, 2024. Absent an order of the Court upon showing of good cause, each side is limited to one forty-page opening brief, one forty-page answering brief, and one twenty page reply brief for all its Daubert motions.

11. Supplementation. Absent agreement among the parties, and approval of the Court, no later than May 19, 2023, the parties must finally supplement, inter alia, the identification of all accused products and claim charts relating each accused product to the asserted claims each product allegedly infringes, invalidity contentions, and all invalidity references.

12. Case Dispositive Motions. No case dispositive motion under Rule 56 may be filed without leave of the Court.

13. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

14. Pretrial Conference. On Feb. 2, 2024, the Court will hold a Rule 16(e) final pretrial conference in Court with counsel beginning at 9 a.m. The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5 p.m. on Jan. 29, 2024. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.

15. Motions *in Limine*. Motions *in limine* shall be separately filed, with each motion containing all the argument described below in one (1) filing for each motion. Any supporting documents in connection with a motion *in limine* shall be filed in one (1) filing separate from the motion *in limine*. Each side (with Plaintiff being one "side", and Defendants collectively being the other "side") shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument and may be opposed by a maximum of three (3) pages of argument, and the party making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply). No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

16. Trial. This matter is scheduled for a **seven** (**7**) day bench trial beginning at 8:30 a.m. on Feb. 12, 2024, with the subsequent trial days beginning at 8:30 a.m., and each day ending at 5:00 p.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

17. ADR Process. Per Standing Order No. 2022-2, Plaintiff and Defendants do not seek referral to a magistrate judge to explore the possibility of alternative dispute resolution.

SO ORDERED this 29th day of August, 2022.

/s/ Richard G. Andrews
UNITED STATES DISTRICT JUDGE

EXHIBIT A – CHRONOLOGICAL SCHEDULE OF ORDERED DATES

Event	Due Date
Production of Defendants' supplements and amendments to ANDAs/FDA correspondence (¶ 3.c)	Within 5 business days of the entry date of this Order
Rule 26(a)(1) Initial Disclosures	Within 5 business days of the entry date of this Order
Initial Disclosures Pursuant to Paragraph 3 of the Delaware Default Standard for Discovery	Within 5 business days of the entry date of this Order
Production of File History for Asserted Patent, (¶ 1.b)	Within 5 business days of the entry date of this Order
Plaintiff's Supplemental Infringement Claim Charts, (¶ 1.c)	July 22, 2022 (for '918 patent) Within 30 days of the entry date of this Order (for '226, '143, and '192 patents)
Defendants' Initial Invalidity Contentions, (¶ 1.d)	Sept. 9, 2022 (for '918 patent) Within 60 days of the entry date of this Order (for '226, '143, '192 patents)
Parties exchange list of claim terms with chart of initial constructions and supporting evidence (¶ 7)	Nov. 4, 2022
Substantial completion of document production (¶ 3.d)	Dec. 14, 2022
Parties exchange list of rebuttal claim constructions and supporting evidence (¶ 7)	Dec. 15, 2022
Meet and Confer regarding Claim Construction	Dec. 22, 2022
Submission of Joint Claim Construction Chart (¶ 7)	Dec. 30, 2022
Deadline to move to join parties or to amend or supplement pleadings (¶ 2)	Jan. 5, 2023
Plaintiff's Opening claim construction brief (¶ 8)	Jan. 20, 2023
Defendants' Responsive claim construction brief (¶ 8)	Feb. 10, 2023
Plaintiff's reply claim construction brief (¶ 8)	Mar. 3, 2023
Defendants' sur-reply claim construction brief (¶ 8)	Mar. 24, 2023
Submission of joint brief (¶ 8)	Mar. 31, 2023
Request additional time for Hearing on Claim Construction (if needed) (¶ 9)	Mar. 31, 2023
Hearing on Claim Construction (¶ 9)	April 14, 2023, 9 a.m.
Final supplementation of accused products and invalidity references (¶ 11)	May 19, 2023

Event	Due Date
Fact Discovery Cut Off (¶ 3.a)	June 16, 2023
Opening expert reports (¶ 10.a)	July 21, 2023
Responsive expert reports (¶ 10.a)	Sept. 1, 2023
Reply expert reports (¶ 10.a)	Oct. 27, 2023
Plaintiff's Sur-reply reports on objective indicia (¶ 11.a)	Nov. 10, 2023
Close of expert discovery (¶ 10.a)	Dec. 22, 2023
Opening Daubert motions (¶ 10.b)	Jan. 5, 2024
Opposition to Daubert motions (¶ 10.b)	Jan. 19, 2024
Replies to Daubert motions (¶ 10.b)	Jan. 26, 2024
Pretrial Order (¶ 14)	Jan. 29, 2024
Pretrial Conference (¶ 14)	Feb. 2, 2024, 9 a.m.
Trial (¶ 16)	Feb. 12, 2024